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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,936	03/21/2002	Pietro Castellacci	70496	4685

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SCARBOROUGH, NY 10510-0827

EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

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DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,936

Applicant(s)

CASTELLACCI, PIETRO

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on July 24, 2000. It is noted, however a certified copy of application no. FI2000A000168 has not been received by the Office in accordance with 35 U.S.C. 119(b).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "101D" as illustrated in Figs. 6 and 8; "105B" as illustrated in Figs. 6, 7 and 9; "303" as illustrated in Figs. 13 and 14; "305D" as illustrated in Figs. 15 and 16; "405E" as illustrated in Fig. 17; "405D" as illustrated in Figs. 17 and 18; and "413" as illustrated in Figs. 17 and 18. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because it includes legal phraseology, i.e. the term "said". Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities:

- a. The cannula and the stem are disclosed as having an end "shaped like the mouthpiece of a flute" at lines 8-9 of page 1; line 6 of page 2; lines 7, 10 and 31 of page 4; and lines 30-31 of page 7. This description apparently is inaccurate. According to *The American Heritage® Dictionary of the English Language, Third Edition* (1992), a flute has a closed end and an opening near the closed end across which the wind is blown. Such a mouthpiece is inconsistent with the structure of the tapered or beveled distal end of the cannula and stem of the present invention as illustrated in the Figures.
- b. On page 1, line 11, it is unclear whether "It" is intended to refer to the cannula or the stem.
- c. On page 3, lines 7 and 8, ---like extension-- apparently should be inserted following each occurrence of the word "tab" in order to maintain consistent terminology for the limitation in the specification.
- d. On page 3, line 27, "4 and 5" apparently should read --5 and 4--.
- e. On page 5, lines 1, 9 and 23, ---like extension-- apparently should be inserted following each occurrence of the word "tab" in order to maintain consistent terminology for the limitation in the specification.

f. On page 7, line 8, "F1" apparently should read --F2--.

Appropriate correction is required.

Claim Objections

6. The claims include reference characters which are enclosed within parentheses. The use of reference characters is considered as having no effect on the scope of the claims. Since the reference characters are not afforded patentable weight, the reference characters enclosed within parentheses apparently should be deleted from the claims. Correction is requested.

7. Claim 1 is objected to because of the following informalities:

- a. In line 2, "which can" apparently should read --adapted to--.
- b. In line 9, "in that" apparently should read --wherein--.
- c. In line 11, "which can" apparently should read --adapted to--.

Appropriate correction is required.

8. Claim 3 is objected to because of the following informalities: in line 4, "of the disposable type" apparently should read --disposable--. Appropriate correction is required.

9. Claim 3 is objected to because of the following informalities: in line 4, "and particularly suited" apparently should read --adapted--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the claim is indefinite because the metes and bounds of the limitation “for a certain stretch”, as recited in line 4, are not clearly defined.

Claim 1 recites the limitation "the opening" in line 4. There is insufficient antecedent basis for this limitation in the claim. There is no opening recited in the claims prior to this recitation.

Claim 1 recites the limitation "the penetrating mouth" in line 6. There is insufficient antecedent basis for this limitation in the claim. There is no penetrating mouth recited in the claims prior to this recitation.

Further regarding claim 1, the pronoun “its”, recited at line 14, renders the claim indefinite. One cannot be certain what “it” is intended to refer to.

Regarding claims 2-8 and 10-12, the terminology used in the preamble of the claims is inconsistent with that used in independent claim 1. As such, it is unclear whether the needle claimed in claims 2-12 is merely a biopsy needle, or if the needle of claims 2-12 can also be used to take “other samples from human or animal organs” as recited in the preamble of independent claim 1.

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Further regarding claims 5 and 6, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Further regarding claim 7, the pronoun "it" renders the claim indefinite. One cannot be certain what "it" is intended to refer to.

Claim 7 recites the limitations "the tab" and "said tab" in lines 2 and 3, respectively. There is insufficient antecedent basis for these limitations in the claim. There is no tab recited in the claims prior to this recitation.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Further regarding claim 12, the pronoun "it" renders the claim indefinite. One cannot be certain what "it" is intended to refer to.

Claim 12 recites the limitations "the tab" and "said tab" in lines 2 and 3, respectively. There is insufficient antecedent basis for

Allowable Subject Matter

12. Claims 1-12 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

13. The following is a statement of reasons for the indication of allowable subject matter:

No prior art of record teach or fairly suggest a biopsy needle, as claimed by Applicant, including an outer cannula having a distal portion with a thickness greater than the thickness of a portion immediately proximal thereto such that the two portions together form a step in an interior wall of the cannula along a plane that is inclined with respect to the longitudinal axis of the cannula; a closing stem within the lumen of the outer cannula; and a withholding element provided with a distal tab-like extension, where the withholding element is disposed between the outer cannula and the closing stem so that the withholding element slides axially therebetween.


Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fuerst ('752) teaches a biopsy needle including a tubular sheath with internal grooves for guiding a slidable stylet. Rubinstein et al. ('186) teach a bone marrow biopsy needle having an inner cannula with deformable pincers. Gordon ('305) teaches a tissue sampling device having a tissue collector formed proximate a distal end of a catheter. Paolo et al. ('121) teach a biopsy device with an outer cannula, an inner cannula and an intermediate cannula having elastic resection means. Mittermeier et al. ('037) teaches a bone marrow biopsy needle including an outer cannula and an inner cannula having a tissue grasping mechanism. Miller et al. ('484) teach a biopsy device for extracting bone marrow tissue samples.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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March 1, 2004